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09/922,694	08/07/2001	Atsushi Suzuki	210377US0	8724

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
UNDERDAHL, THANE E	
ART UNIT	**PAPER NUMBER**
1651	

NOTIFICATION DATE	DELIVERY MODE
06/01/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	09/922,694	SUZUKI ET AL.	
	Examiner	Art Unit	
	Thane Underdahl	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-55,63-65,69 and 70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-55,63-65,69 and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Applicant's Arguments— 35 U.S.C § 112

In the response submitted by the applicant on 2/26/06 the 35 U.S.C § 112 1st and 2nd paragraph rejection of claims 46-52 and 56-65 for written description and being indefinite are withdrawn.

Response to Applicant's Arguments— 35 U.S.C § 103

In the response submitted by the applicant on 2/26/07 , the 35 U.S.C § 103 (a) rejection of claims 46-52 and 63-65 over Abraham in view of were considered but not found persuasive.

The Applicant argues that while Abraham teach a composition of ferulic acid, caffeic acid, and chlorogenic acid is added to coffee that he does not teach the composition is administered to treat hypertension. The applicant further argues the additional teachings of Hsu and Yokozawa et al. do no motivate the application of the Abraham's composition to treat hypertension since Hsu and Yokozawa only teach that chlorogenic acid and caffeic acid are useful for treating hypertension.

However, the examiner points out that since Yokozawa and Hsu teach the addition of chlorogenic and caffeic acid to the diet controls hypertension. It would be obvious to one of ordinary skill in the art to use the composition of Abraham in this capacity since it contains substantial amounts of these anti-hypertensives. The Applicant argues, "there is no such motivation to add ferulic acid to this composition and to expect the same result". However since the composition of Abraham has at least

two identifiable anti-hypertensives as taught by Yokozawa and Hsu and Abraham has shown that their compositions is edible, the motivation is present to apply the composition of Abraham to treat hypertension. As for the reasonable expectation of success, Yokozawa (page 107, table 1) and Hsu (Crataegus, Figure 1) show that these compounds do treat hypertension so there is a ground for reasonable expectation of success. So it would be obvious to use the composition of Abraham that contains ferulic acid, caffeic acid, and chlorogenic acid to treat hypertension with the motivation and reasonable expectation of success provided by Yokozawa and Hsu.

The Applicant argues that no motivation exists to add ferulic acid a composition of caffeic acid and chlorogenic acid. However such a composition has already been taught by Abraham and no motivation is required to add the three acids together in a composition. The question if there is motivation to use Abraham's composition to treat hypertension has been affirmatively answered by Yokozawa and Hsu above.

That Applicant continues to argue that the method of treating hypertension is obvious because of there are "clear advantages of co-administration of ferulic acid with caffeic acid and/or chlorogenic acid". The Applicant directs the Examiner's attention to Table 1 of the specification. The Applicant claims that the results of Test Plots 4-6 show a synergistic effect of co-combining these acids. However, one of ordinary skill in the art would recognize that to show synergism the effect of the two components must be *greater* than the sum of their individual effects. This is not the case shown in the data in table 1. When accounting for the error, the effects of the various compositions of ferulic, caffeic and chlorogenic acids are simply on the systolic blood pressure are simply the

sum of their individual effects. For example, the mean values of Ferulic acid (-7.8), added to the mean values of Caffeic acid (-4.1) or Chlorogenic acid (-3.2) are -11.9 and –11 respectively which are within the experimental results of their combination shown in Table 1. Therefore synergistic effects are not present.

The Applicant continues to argue that there is no specific motivation provided to combine the teachings of Ghai et al., Hsu, Abraham and Takazawa et al. However it is clear that each reference pertains to nutraceuticals and herbal compositions and as such are analogous art. Ghai et al. simply teach that nutraceuticals in raw and process foods can be optimized to treat a diseased condition (Ghai see abstract). One of ordinary skill in the art would recognize that optimizing the ingredients in their composition is imperative to properly treat a condition such as hypertension. Therefore one of ordinary skill in the art would recognize that optimizing the composition of Abraham with the teachings of Ghai in view of the information provided by Hsu and Takazawa et al. is prima facia obvious.

Furthermore one of ordinary skill in the art would recognize the amounts of these acids in a composition are result effective variables. Absent any teaching of criticality by the applicant concerning the concentration of these acids it would be *prima facie* obvious that one of ordinary skill in the art would recognize these limitations are result effective variables which can be met as a matter of routine optimization (M.P.E.P. § 2144.05 II).

Therefore the rejection is maintained and repeated below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 46-52 and 63-65 stand rejected under 35 U.S.C 103(a) as being unpatentable over Abraham (XP-001148404, 1996) in view of Hsu (US 5,958,417) and further in view of Ghai et al. (US 5,955,269) and Yokozawa et al. (Phytotherapy Research, 1995).

The claims are to a food supplemented consisting of ferulic acid and caffeic acid, chlorogenic acid or a combination of caffeic acid and chlorogenic acid. Abraham discloses a dietary constituent comprising a combination of chlorogenic acid, caffeic acid and ferulic acid (Table 1). The weight ratio of these acids is between 0.01 and 50 (Table 1). These phenolic compounds occur in some of the commonly consumed vegetables, fruits and beverages (page 19, column 1). Abraham does not expressly disclose that the referenced dietary constituents are used in the treatment of hypertension. However, Hsu ('417) addresses this limitation by disclosing that the active principles, chlorogenic acid and caffeic acid, found in the herbal substance, Crataegus, are used to treat hypertension (column 2, lines 59-61). Yokozawa et al. teach that caffeic acid alone has anti-hypertensive properties (page 195, Table 1, Day 18 and Day 24).

One of ordinary skill in the art would have been motivated to combine the dietary constituents disclosed by Abraham to make a composition for treatment of hypertension as discussed by Hsu because of the need for alternatives to conventional pharmaceuticals currently used to treat hypertension, with an expectation of fewer harmful side effects. Hsu and Yokozawa et al. provide a reasonable expectation of success by teaching Caffeic acid both in Crataegus and in isolated form have hypertensive properties.

The examiner cites Ghai et al. (US 5, 955,269) that discloses processed foods, or foods fortified with nutraceuticals and the methods of adjusting the combination and level of these nutraceutical compounds in a supplement or in food products to achieve added nutritional or therapeutic benefit (col. 25, lines 1-3, col. 26, lines 43-50 and col. 27, lines 19-25). The reference further teaches that nutraceutical compounds can be administered by inhalation; orally as tablets, capsules, or liquid preparations; controlled release formulations; or as food supplements (col. 25-26). Table 1 (col. 23, lines 41-65) further discloses examples of phenolic acids, such as caffeic, chlorogenic, and ferulic acids as examples of food substances that can be used as nutraceuticals. The reference does not disclose the anti-hypertensive properties of caffeic, chlorogenic, or ferulic acids. However, the teachings of Hsu, as discussed above, do address this limitation. It would have been obvious to one of ordinary skill in the art to combine ferulic acid with chlorogenic acid and caffeic acid as taught by Ghai to obtain synergistic effects in the treatment of hypertension. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a nutraceutical

supplement to fortify foods or beverages as taught by Ghai, and to use said foods or beverages in the treatment of hypertension as taught by Hsu, with an expectation of reduced toxicity.

Therefore the references listed above renders obvious claims 46-52 and 63-65.

Response to Applicant's Arguments— Double Patenting

In the response submitted by the applicant on 2/26/07 , the double patenting rejection of claims 40-42, 63-65, 69, and 70 over claims 1-11 of U.S. Patent # 6,310,100 in view of Yokozawa et al. were considered but not found persuasive.

The applicant argues that "the co-administration of ferulic acid with 'at least one other anti-hypertensive compound.'" Is such a broad genus that does not grant one of ordinary skill in the art possession of the invention given the large variety of anti-hypertensive compounds. Never the less the claim does read on the co-pending application and Yokozawa et al. does indeed teach caffeic acid as a hypertensive compound, therefore the combination of teachings reads on the current application in the absence of unexpected results.

The Applicant claims that the obviousness of this double patenting rejection is overcome by the unexpected results shown by the synergism of the caffeic, chlorogenic and ferulic acids together to lower hypertension. As mention above and re-iterated here one of ordinary skill in the art would recognize that to show synergism the effect of the two components must be *greater* than the sum of their individual effects. This is not the case shown in the data in table 1 of the specification. When accounting

for the error, the effects of the various combinations of ferulic, caffeic and chlorogenic acids are simply on the systolic blood pressure are simply the sum of their individual effects. For example, the mean values of Ferulic acid (-7.8), added to the mean values of Caffeic acid (-4.1) or Chlorogenic acid (-3.2) are -11.9 and –11 respectively which are within the experimental results of their combinations shown in Table 1. Therefore synergistic effects are not present. The applicant further specifies synergism at the one hour time point. However the error for ferulic acid is three times larger than the value at that time point. When accounting for that error the values for the combinations of those acids are still the sum of the individual values. Therefore at both the 10 minute time period and after one hour time period, synergism is not present.

Therefore the rejection is maintained and repeated below.

Claims 40-42, 63-65, 69, and 70 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,310,100 B1 in view of Yokozawa et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions disclose treatments for hypertension comprised of ferulic acid or a derivative thereof. The therapeutic compositions comprising ferulic acid and its derivatives may further comprise pharmaceutical products, nutritional supplements or products, and foods. The reference does not specifically claim chlorogenic or caffeic acid in combination with ferulic acid, but in claim 5 it does disclose a composition "consisting essentially of ferulic acid or a derivative thereof, and at least one other anti-hypertensive compound," which would encompass chlorogenic and caffeic acid. One of ordinary skill

in the art would be motivated to combine chlorogenic and caffeic acids, which are known anti-hypertensive agents to a composition comprising ferulic acid with the expectation of successful treatment of hypertension with such a composition.

Claims 40-55, 63-65, 69 and 70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 11/209672. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are directed to an agent for preventing, improving or treating hypertension. The agent consists of caffeic acid, chlorogenic, and ferulic acid and a component that stimulates the central nervous system. Although the instant claims do not include a component the stimulates the central nervous system, it would be obvious to use compounds such as sugar alcohols because not only do they stimulate the central nervous system, but they improve the taste of the oral composition. One of ordinary skill in the art would be motivated to combine the chlorogenic, caffeic acid, and ferulic acid in a composition for treating hypertension because the combination would most likely have additive effects, if not synergistic effects in treating hypertension.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 46 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Abraham et al.

These claims are drawn to a composition comprising a food ingredient, and (a) an isolated or purified ferulic acid or an ester thereof, or a pharmaceutically acceptable salt thereof, and (b) an isolated or purified caffeic acid and/or chlorogenic acid, or a pharmaceutically acceptable salt thereof. Components (a)/(b) are added to the food ingredient at a weight ratio from 0.01 to 50 and the food is not an unsupplemented food. Claim 50 further limits that the food ingredient is an oil or fat-containing food.

Abraham et al. teach a composition that comprises 20 mg/kg of chlorogenic acid, 20 mg/kg caffeic acid and 15 mg/kg of ferulic acid that is combined with corn oil (Abraham, Table 1 Code C +D). The weight ratios of the combinations of the acids are all within the range of 0.01 to 50. Therefore the reference anticipates claims 46 and 50.

In summary no claims, as written, are allowed for this application.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached during regular business hours, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651

Leon B. Lankford Jr
Primary Examiner
Art Unit 1651